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EXAMINER	
HAMA, JOANNE	
ART UNIT	PAPER NUMBER
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,736	BRANCACCIO ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 40-42* is/are pending in the application.

4a) Of the above claim(s) *10 and 19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-18,24,25 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 2 in the reply filed on December 18, 2006 is acknowledged. Applicant also elected "stable modification" (see claim 2) and "homologous recombination" (see claim 5) as part of the restriction requirement. With regard to the species election, Applicant elected "transcriptional level" (see claim 2), "transverse aortic constriction" (see claims 8 and 9), and "129SV" (see claim 17). The traversal is on the ground(s) that examination of all the claims would not constitute a serious burden (Applicant's response, page 6, 2nd parag.). This is not found persuasive because as indicated in the Restriction Requirement, October 23, 2006, pages 4-6, the searches of the inventions are burdensome because the searches are not coextensive.

Applicant indicates that while it is agreed that the inventions indicated by the Examiner are separately patentable, traversal is based on the pending claims being so linked as to form a single general inventive concept under PCT Rule 13.1. Thus, the claims should be examined together (Applicant's response, page 6, 3rd parag.). In response, the Examiner has indicated that the groups do not share a special technical feature, as melusin, the special technical feature, was known at the time of filing (Restriction Requirement, October 23, 2006, page 4). Thus, the inventions were found to lack unity of invention.

Applicant indicates that in accordance with the MPEP, the claims identified by the Examiner as Groups 2, 4, 6, stable or transient modification of melusin expression, and different levels of regulating melusin expression are linked to form a single general

inventive concept, see MEPE § 1850 III. A. Combinations of Different Categories of Claims (8th Ed., Rev. 3, August 2005) (Applicant's response, page 6, 4th parag.). Applicant indicates that it was alleged in the Action that the inventions listed by the Examiner do not relate to a single inventive concept because they lack the same special technical feature under PCT Rule 13.2. Applicant indicates that the special technical feature linking the pending claims is that they all involve a non-human transgenic animal having altered melusin expression (Applicant's response, page 7, 1st parag.). In response, as indicated in the Restriction Requirement, October 23, 2006, page 4, Unity of Invention occurs between different categories of inventions. However, the allowed combinations do not include multiple products, multiple methods of using said product, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. In Group 2, the Examiner has drawn the invention to a non-human transgenic animal, a method for screening for compounds using the claimed non-human animal, and to a method of making the non-human animal. As indicated in MPEP § 1850, allowed combinations do not include multiple methods of using said product (note that the additional method of using the claimed non-human animal is in a separate Group 4), and multiple products (note that the cells obtained from the non-human animal and the method of using the cells are in Group 6). Thus, according to MPEP § 1850, Lack of Unity was proper.

Applicant indicates that claim 1 is a generic or linking claim (Applicant's response, page 8, 3rd parag.). In response, claim 1 is not a linking claim because this is case a 371 is and is not subject to analysis under linking claim practice.

Applicant indicates that the Action alleges, "a proper search and examination cannot be carried out" on the pending claims. This allegation contradicts the instruction to examiners in MPEP § 704.01 that "full faith and credit should be given to the search and action of the previous examiner unless there is a clear error in the previous action or knowledge of the prior art." Applicant indicates that there is no evidence of either clear error or knowledge of other prior art. In response, while Applicant indicates MPEP §704.01 for the instant Examiner's reliance upon a previous Examiner's search strategies, MPEP §704.01, this is not guidance as to whether or not an Examiner can or cannot restrict mid-prosecution. The instant Examiner refers to MPEP § 811.03 which indicates, "(w)here a requirement to restrict is made and thereafter withdrawn as improper, if restriction becomes proper at a later stage in prosecution, restriction may again be required." The instant Examiner has determined that restriction is proper at this stage in prosecution, as indicated by the Restriction Requirement of October 23, 2006. Note that the Restriction identified multiple inventions and the instant Examiner has determined that a proper search and examination cannot be carried out unless the claims were restricted (Restriction Requirement, October 23, 2006, page 2).

The requirement is still deemed proper and is therefore made FINAL.

Claims 10, 19-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 18, 2006.

Claims 1-9, 11-19, 24, 25, 40-42 are under consideration. Note that per further restriction, the claims are drawn to "stable" modification (claim 2) and that the genetic approach of the non-human transgenic human animal is "homologous recombination" (claim 5). Per species election, the claims are drawn to modification at the "transcriptional" level (claim 2), that the hypertensive condition is determined by surgical operation (claims 8-9), and that the strain of mice is 129SV (claim 17).

It is noted that Applicant filed response to the Non-Final Action of May 6, 2006 on July 27, 2006. The Examiner will respond to Applicant's responses in this Office Action.

Information Disclosure Statement

Applicant filed an Information Disclosure Statement (IDS) on July 27, 2006. The IDS has been considered.

Withdrawn Rejections/Objections

Specification

Applicant's arguments, see page 6, of Applicant's response, filed July 27, 2006, with respect to the objection to the specification have been fully considered and are persuasive. Applicant indicates that clarification is requested because it is not clear to Applicant what the Examiner considers "essential material" or an improper incorporation by reference. The instant Examiner has looked through Applicant's case and has not found anything which appears to be an improper incorporation by reference. The objection of the specification has been withdrawn.

35 U.S.C. § 101- "Use claims"

Applicant's arguments, see page 16 of Applicant's response, filed July 27, 2006, with respect to the rejection of claims 18, 19, 23 have been fully considered and are persuasive. Applicant amended the claims and claim 18 recites active steps. The rejection of claim 18 has been withdrawn. The rejection of claims 19 and 23 are withdrawn as the claims have been withdrawn from consideration, per the Restriction requirement, see above.

35 U.S.C. § 112, 2nd parag.

Applicant's arguments, see page 16 of Applicant's response, filed July 27, 2006, with respect to the rejection of claims 18, 19, 23 have been fully considered and are persuasive. Applicant has amended the claim 18 to include active steps involved in the method. The rejection of claim 18 has been withdrawn. The rejection of claims 19 and 23 are withdrawn as the claims have been withdrawn from consideration, per the Restriction requirement, see above.

35 U.S.C. § 112, Written Description

Applicant's arguments, see pages 6-8 of Applicant's response, filed July 27, 2006, with respect to the rejection of claims 1-25 have been fully considered and are persuasive. Applicant indicates that the main objection appears to be that the Applicant allegedly teach only one means for altering melusin expression. Although Applicant's

work has concentrated on homologous recombination to inactivate melusin expression, Applicant teaches other embodiments of the invention, including administration of antisense and RNA interference. In response, since the claims have been restricted to only homologous recombination (claim 5), the issues regarding the administration of antisense and RNA interference is moot. As for Written Description being raised for "homologous recombination," there are no issues regarding Written Description as they apply to homologous recombination. Thus, the rejection regarding these issues is withdrawn.

Regarding the issue that the claims are readable in increased expression (Office Action, May 3, 2006, page 3, 3rd parag. under the Written Description heading), wherein the claims are readable on any species of melusin, the claims have been restricted to only homologous recombination (claim 5), and thus, the issues regarding overexpression are moot. Thus, the rejection regarding this issue is withdrawn.

Regarding the issue that the claims are readable on overexpression in cells that notrmally do not express melusin (Office Action, May 3, 2006, page 4, 3rd parag.), the claims have been restricted to only homologous recombination (claim 5) and thus, the issue of whether or not cells that normally do not express melusin do now express melusin is moot. The rejection regarding this issue is withdrawn.

The rejection of 1-9, 11-19, 24, 25 has been withdrawn. It is noted that the rejection of claims 10, 20-23 is withdrawn as the claims are withdrawn from consideration, per the Restriction requirement, see above.

New/Maintained Rejections/Objections

Claim Objections

Claims 1-9, 11-19, 24, 25, 40-42 are newly objected to because of the following informalities: claims 1, 2, 5, 17 include embodiments drawn to non-elected subject matter. Claims should be amended to reflect the claimed invention. Appropriate correction is required. Claims 3, 4, 6, 7, 8, 9, 11-18, 40-42 are included in the objection as they depend on claims 1, 2, 5, 17 and do not overcome the issue of being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9, 11-19, 24, 25, 40-42 are newly rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial utility or a well established utility. According to the Revised Utility Examination Guidelines, see the Federal Register, Vol. 66, No. 4, pp. 19092-1099 (January 5, 2001), also available at http://uspto.gov/web.menu.utility.pdf, the following definitions of credible, specific, and substantial apply.

A credible utility is one that a person of ordinary skill in the art would accept as currently available. An assertion is considered credible unless (a) the logic underlying the assertion is seriously flawed, or (b) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. Credibility as used in this context

refers to the reliability of the statement based on the logic and facts that are offered by the Applicant to support the assertion of utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use.

A specific utility is one that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention.

A substantial utility is one that defines a real world use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context of use are not substantial utilities. Research that involves studying the properties of the claimed product itself does not constitute a substantial utility.

See also MPEP 2107-2107.02, and *Brenner, Comr. Pats. v. Manson*, 148 USPQ 689 (US SupCt 1966).

The instant claims are drawn to a non-human transgenic animal comprising a disruption in its melusin gene. The claimed animal exhibits at least impaired heart hypertrophy, heart dilation, and heart failure. The specification identifies the following uses for the claimed non-human animals and methods: 1) the use of the non-human animals in a study for heart pathology (e.g. see claim 19) and 2) the use of the non-human animals in testing drugs aimed in preventing heart failure (specification, page 1, 1st parag., and page 11, 2nd parag.). With regard to the method of generating the claimed non-human transgenic animals (e.g. claims 24-25), the specification only provides a single use for these products, which is their use to produce a non-human

animal with a homozygous disruption in the endogenous melusin gene. Thus, the utility of the heterozygous non-human animal rests on the utility of the homozygous transgenic non-human animal.

In regards to asserted utility 1), as identified above, the stated utility of the non-human animals for studying heart pathology does not constitute a real world utility and therefore is not a substantial utility, but rather represents further research on the product to identify or reasonably confirm a real world utility. As stated in the Guidelines set forth above, research that involves studying the properties of the claimed product itself does not constitute a substantial utility. Further, such an asserted utility constitutes a general, rather than a specific utility, as all knockout non-human animals can be used to study the effects of the loss of function of the gene that is disrupted. Therefore, asserted utility 1) does not meet the standard for a specific and substantial utility.

In regards to asserted utility 2), as identified above, the specification teaches that mice comprising a disruption in its genome of the melusin gene (specification, page 13, 1st parag.) exhibit phenotypes of heart hypertrophy, heart dilation, and heart failure following chronic hypertension (specification, page 15, parags. 2 and 4). While the specification provides this teaching, neither the specification nor the art provide any guidance that there is any relationship between melusin and these phenotypes. As discussed further in the Enablement section, an artisan cannot readily predict phenotypes in any transgenic knockout non-human animal. In addition to this issue, neither the specification nor the art provide any guidance that the phenotypes are related to any disease or disorder such that the claimed non-human animals can be

used as model for disease and in methods for screening for drugs aimed at treating heart failure.

Thus, in view of the discussion above, the skilled artisan would not find any of the asserted utilities of the transgenic non-human animals, cells, and methods of using encompassed by the claims to be specific and substantial, or well-established.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11-19, 24, 25, 40-42 remain rejected in modified form under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record, May 3, 2006.

It is noted that upon further consideration, the enablement rejection no longer has an enabled scope. As discussed below, the specification and art lacks enablement for an artisan to arrive at the claimed invention.

Response to Applicant's rebuttals filed July 27, 2006 follows the rejection.

At the time of filing, the art did not consider the phenotype of a knockout or transgenic mouse to be predictable. In addition, the art did not consider the correlation between any observed mouse phenotypes and human disease phenotypes as

predictable. Doetschmann et al. teaches that "[o]ne often hears the comment that genetically engineered mice, especially knockout mice, are not useful because they frequently do not yield the expected phenotype, or they don't seem to have any phenotype" (Doetschmann,1999, Lab. Animal Sci., 49: 137-143, see page 137, column 1, paragraph 1). Doetschmann provides numerous examples of instances in which genes considered well-characterized *in vitro* have produced unexpected phenotypes or indiscernible or no phenotypes in transgenic or knockout mice. Moens et al. further teaches that different mutations in the same gene can lead to unexpected differences in the phenotype observed. Moens et al. shows that two mutations produced by homologous recombination in two different locations of the N-myc gene produce two different phenotypes in mouse embyronic stem cells, one leaky and one null (Moens et al., 1993, Development, 119: 485-499). Further, the art demonstrates the unpredictability of making a mouse model for human disease by disrupting the murine gene. Jacks et al. teaches that although retinoblastoma (Rb) gene mutations in humans are associated with retinal tumors, Rb gene knockout mice had tumors in the pituitary gland rather than the retinas (Jacks et al., 1992, Nature, 359: 295-300). Likewise, whereas HPRT deficiency in humans is associated with Lesch-Nyhan syndrome, a severe neurological disorder, HPRT-deficient mice are phenotypically normal (Kuehn et al., 1987, Nature, 326: 295-298 and Jaenisch, 1988, Science, 240: 1468-1474). Thus, the art at the time of filing clearly establishes the unpredictability of determining the phenotype of transgenic or knockout mouse even when the activity of the gene has been extensively studied *in vitro*, and further establishes the unpredictability of

generating a mouse model for human disease based on the activity of the gene in humans. As these issues apply to the instant invention, while the specification teaches that mice comprising a disruption in their melusin gene were made (specification, Example 1) and that the mice exhibit certain phenotypes (specification, Examples 2-4), the specification and art provide no guidance that humans comprising a homozygous disruption in melusin also exhibit these phenotypes. That is, nothing in the art or specification teach that a melusin gene disruption in humans results in cardiac cardiomyopathy, such that the claimed mice can be used as a model of a human disease or condition. Thus, the enabled use of the claimed mice is unclear and the claims are rejected.

The claims broadly encompass any transgenic non-human animal. However, at the time of filing, the art teaches that the only known non-human animal in which embryonic stem (ES) cells can be obtained was for mouse. This is because mice are the only mammals in which ES cells can be generated and which chimerism from ES cells extend to the germline (Murray, et al. 1999, *Transgenic Animals in Agriculture*, CAB International: Oxon, pages 58-61, page 60 2nd parag.). Further, according to Murray, et al., the "isolation of ES cells has not been accomplished unequivocally in other species, including in domestic livestock (Murray, et al., page 59, lines 3-4)." As the teachings of Murray et al. apply to the instant invention, while the specification and the art teach how to make transgenic mice with ES cells, neither the specification nor the art teaches how to obtain ES cells from other species of animals such that an artisan is enabled for the fullest breadth of the claims. Thus, the claims are rejected.

In addition to the above issues, the claims are drawn to transgenic non-human animals that have no phenotype (e.g. claim 1). Nothing in the specification teaches an artisan how to use transgenic non-human animals that have no phenotype.

Therefore, in view of the art recognized inability in obtaining ES cells such that knockout animals can be obtained from any species of animal, the unpredictability in determining the phenotype of knockout non-human animal even when the activity of the gene has been extensively studied *in vitro*, the unpredictability of generating a non-human animal model for human disease, and the unpredictability in correlating any observed phenotype in a knockout mouse with gene disruption as acknowledged by both the prior art and the specification, and the breadth of the claims as written, it would have required undue experimentation to practice the instant invention as claimed.

Response to Arguments

Applicant's arguments filed July 27, 2006 have been fully considered but they are not persuasive.

Applicant indicates that generation and study of heart hypertrophy, dilation, and failure in transgenic animals are well known to the skilled artisan; that the techniques to generate hypertensive conditions in transgenic animals such that they develop heart hypertrophy, dilation, and failure have been extensively described; that the techniques to study heart hypertrophy, dilation, and failure in transgenic mice are well known; that the techniques to generate transgenic animals have been extensively described since early 1990 (Applicant's response, page 9-11). In response, as discussed above in the

rejection, the issue at hand is that the specification and the art teaches that there is unpredictability in arriving at transgenic animal models of disease and that an artisan cannot reasonably predict that the knockout mice made in the specification is a model of a human condition. In addition to this issue, the art also teaches unpredictability in arriving at the full breadth of any knockout non-human animal encompassed in the claims. As such, the Enablement rejection arises because it is not entirely clear what use the claimed mice have, if there is no relationship between the phenotypes exhibited by the mice and a human condition.

Regarding the protocol for screening compounds pharmacologically active in prevention and treatment of heart dilation and failure and that the melusin null mice used for testing and validating both novel and known compounds (Applicant's response, page 11), the rejection above discusses that it is unclear what relationship melusin and the phenotypes exhibited by the mice described in the specification have, such that an artisan can focus on a phenotype in the mouse to screen for compounds that treat the phenotype and such that the compound can be used to treat the same condition in a human. While the specification generally indicates a relationship of melusin with beta1D integrin (specification, page 4) and indicates in the response to the Office Action that there are consequences of beta1 integrin mutations in cardiac structure and function (Applicant's response, pages 13-14), the teachings of beta1 integrin do not teach what relationship melusin has with the phenotypes exhibited in the transgenic mice and also does not teach that the disruption of melusin has any relationship with any disease. Subsequently, because it is unclear what model of disease the mice

described in the specification are for and it is unclear whether there is a relationship between the phenotype and the gene, an artisan cannot reliably use the mice described in the specification for screening of any medicaments used in heart dilation or failure treatments.

With regard to Applicant addressing the genetic approaches to generate transgenic animals with altered melusin expression RNA interference or antisense (Applicant's response, page 14), Applicant provides a response to the Examiner's rejection. However, because the claims being examined, per the Restriction requirement, see above, are not drawn to the use of RNA interference or antisense, Applicant's arguments are moot. Thus, the rejection, as it applies to this issue is withdrawn.

Applicant indicates that the techniques to transiently modify the gene expression in transgenic mice as the tetracycline system are well known in the art and are widely described in the literature (Applicant's response, page 15). In response, the claims being examined, per the Restriction requirement, see above, are not drawn to the use of transient modification of the claimed animals. Applicant's arguments are moot. Thus, the rejection, as it applies to this issue is withdrawn.

With regard to the issue that, "(h)owever the applicant submit that these phenotypes are not exhibited when using hypertensive drugs," the Examiner indicates that administration of phenylephrine or angiotensin II at sub-pressor doses which do not increase blood pressure and that the null melusin heart undergoes a normal hypertrophy response (specification, Example 3). Applicant indicates that this result

does not contradict the fact that shown in Applicants' specification that melusin null mice have a defective response when exposed to conditions that induce hypertension (Applicant's response, page 15). In response, the claims being examined, per the Restriction requirement, see above, are not drawn to the use of hypertensive drugs. Applicant's arguments are moot. Thus, the rejection, as it applies to this issue is withdrawn.

Regarding the issue of the definition of heart pathologies being totally superfluous as it is common knowledge to any cardiologist (Applicant's response, page 15), the Examiner finds the argument persuasive and withdraws the rejection as it applies to this issue.

It is noted that the rejection of claims 10, 20-23 is withdrawn as the claims are withdrawn from consideration, per the Restriction requirement, see above.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JH

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PRIMARY EXAMINER